

Food and Drug Administration, HHS

§ 10.19

matter and includes action on a new drug application, new animal drug application, or biological license.

Participant means any person participating in any proceeding, including each party and any other interested person.

Party means the center of the Food and Drug Administration responsible for a matter involved and every person who either has exercised a right to request or has been granted the right by the Commissioner to have a hearing under part 12 or part 16 or who has waived the right to a hearing to obtain the establishment of a Public Board of Inquiry under part 13 and as a result of whose action a hearing or a Public Board of Inquiry has been established.

Person includes an individual, partnership, corporation, association, or other legal entity.

Petition means a petition, application, or other document requesting the Commissioner to establish, amend, or revoke a regulation or order, or to take or not to take any other form of administrative action, under the laws administered by the Food and Drug Administration.

Presiding officer means the Commissioner or the Commissioner's designee or an administrative law judge appointed as provided in 5 U.S.C. 3105.

Proceeding and *administrative proceeding* means any undertaking to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action.

Public advisory committee or *advisory committee* means any committee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other subgroup of an advisory committee, that is not composed wholly of full-time employees of the Federal Government and is established or utilized by the Food and Drug Administration to obtain advice or recommendations.

Public Board of Inquiry or *Board* means an administrative law tribunal constituted under part 13.

Public hearing before a public advisory committee means a hearing conducted under part 14.

Public hearing before a Public Board of Inquiry means a hearing conducted under part 13.

Public hearing before the Commissioner means a hearing conducted under part 15.

Regulations means an agency rule of general or particular applicability and future effect issued under a law administered by the Commissioner or relating to administrative practices and procedures. In accordance with §10.90(a), each agency regulation will be published in the FEDERAL REGISTER and codified in the Code of Federal Regulations.

Regulatory hearing before the Food and Drug Administration means a hearing conducted under part 16.

Secretary means the Secretary of Health and Human Services.

The laws administered by the Commissioner or the laws administered by the Food and Drug Administration means all the laws that the Commissioner is authorized to administer under §5.10.

(b) A term that is defined in section 201 of the Federal Food, Drug, and Cosmetic Act or part 1 has the same definition in this part.

(c) Words in the singular form include the plural, words in the masculine form include the feminine, and vice versa.

(d) Whenever a reference is made in this part to a person in FDA, e.g., the director of a center, the reference includes all persons to whom that person has delegated the specific function involved.

[44 FR 22323, Apr. 13, 1979, as amended at 46 FR 8455, Jan. 27, 1981; 50 FR 8994, Mar. 6, 1985; 54 FR 6886, Feb. 15, 1989; 54 FR 9034, Mar. 3, 1989; 59 FR 14363, Mar. 28, 1994]

§10.10 Summaries of administrative practices and procedures.

To encourage public participation in all agency activities, the Commissioner will prepare for public distribution summaries of FDA administrative practices and procedures in readily understandable terms.

§10.19 Waiver, suspension, or modification of procedural requirements.

The Commissioner or a presiding officer may, either voluntarily or at the